Attachment 3 - 510(k) Summary K041739

Submitter:	Edwards Lifesciences LLC
Contact Person:	Elizabeth Moran, Regulatory Affairs Specialist
Date Prepared:	September 13, 2004
Trade Name:	Edwards E360 surgical ablation device
Classification Name:	Class II, Laser Surgical Instrument
Predicate Device(s):	Malleable Surgical Lightstic 180 (Marketed under the trade name of Edwards surgical ablation handpiece) (K013901) AFx FLEX 10 Accessory for the AFx Microwave Ablation System (K013946) Edwards Retrograde Cardioplegia Cannula (K880103) Edwards Swan-Ganz™ Synthetic ControlCath Thermodilution Catheter (K001063)
Device Description:	The Edwards E360 surgical ablation device is a sterile, single-use, disposable device for delivery of 980 nm laser energy in the contact mode.
Indications for Use:	The Edwards E360 surgical ablation device is intended to be used as a surgical instrument for coagulation of soft tissue (including cardiac tissue) in conjunction with or without endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, cystoscopes, gastroscopes, and colonoscopes), and coagulation of soft tissue in the contact mode in both open or closed surgical procedures (with or without handpiece). The Edwards E360 surgical ablation device is indicated for use in medicine and surgery with 980 to 1064 nm wavelength laser energy in the following surgical specialties: General Surgery, Cardiac/Thoracic Surgery, Plastic Surgery, and Dermatology.

Comparative Analysis:	It is demonstrated that the Edwards E360 surgical ablation device is comparable to the predicate device in design, intended use, materials, and principal of operation.
Functional/Safety Testing:	The Edwards E360 surgical ablation device has successfully completed design verification testing.
Conclusion:	The Edwards E360 surgical ablation device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2008

Edwards Lifesciences, LLC
c/o Ms. Elizabeth Moran
Regulatory Affairs Specialist
One Edwards Way
Irvine, CA 92614

Re: K041739
Trade Name: Edwards E360 Surgical Ablation Device
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology
Regulatory Class: II (two)
Product Code: OCL, GEX
Dated: September 13, 2004
Received: September 14, 2004

Dear Ms. Moran:

This letter corrects our substantially equivalent letter of September 29, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

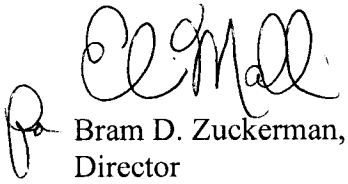
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2 - Indications for Use Statement

510(k) Number (if known): K041739

Device Name: Edwards E360 surgical ablation device

Indications for Use:

The Edwards E360 surgical ablation device is intended to be used as a surgical instrument for coagulation of soft tissue (including cardiac tissue) in conjunction with or without endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, cystoscopes, gastroscopes, and colonoscopes), and coagulation of soft tissue in the contact mode in both open or closed surgical procedures (with or without handpiece).

The Edwards E360 surgical ablation device is indicated for use in medicine and surgery with 980 to 1064 nm wavelength laser energy in the following surgical specialties: General Surgery, Cardiac/Thoracic Surgery, Plastic Surgery, and Dermatology.

K041739

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vision of Cardiovascular Devices
: 0(k) Number_____

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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